



JAN 10 1997

Philips Medical Systems

K964318

Summary of Safety and Effectiveness

CLASSIFICATION NAME: Computed Tomography X-ray System
Class II -21 CFR 892.1750

COMMON/USUAL NAME: CT X-ray System

TRADE/PROPRIETARY NAME: Philips TOMOSCAN AVE Upgrade

ESTABLISHMENT No. 1217116

PERFORMANCE STANDARDS: 21 CFR Part 1020.33, IEC-601, and UL-187.

SYSTEM DESCRIPTION:

The Philips Tomoscan AV Expander Upgrade is an upgrade package to be installed on the existing Tomoscan SR 7000 (K924082). It is comprised of components and capabilities taken from the TOMOSCAN AVE CT system which has been cleared for commercial distribution by Premarket Notification submission K954255.

Identified components of the Expander Upgrade are the Rapidview Reconstructor, and an interface package; the included capabilities include a 7 mm slice thickness, and table speeds of 7 and 14 mm/sec. The AV Expander Upgrade does not alter the intended use of the CT system to which it is attached, nor does it differ from the SR8000. The resultant changes in specification do not affect clinical applications or effectiveness of the device. The X-ray tube and the different detectors will be the major difference between an upgraded SR 7000 and the Tomoscan AVE (SR 8000).

The AVE Upgrade is intended to address the primary operational differences between the Tomoscan SR 8000 and SR 7000:

Hardware/Software Content

- Rapidview Reconstructor
- Interface package (Net Interface)

Functional Changes

- 1 sec reconstruction
- 7 mm slice thickness,
- Table speeds of 7 and 14 mm/sec

SAFETY INFORMATION:

Computed Tomography is a mature technology with which the industry and users have many years of experience. These devices must comply with the appropriate sections of the Radiation Control for Health and Safety Act. A Product Report will be submitted prior to first delivery. Additionally, Philips CT systems are designed to be in compliance with National and International safety standards.

Philips Medical Systems
North America Company
710 Bridgeport Avenue
Shelton, CT 06484-4708
Tel: (203) 926-7674
Fax: (203) 929-6099